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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,344	JIRA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 1-12 are pending in the application, with claims 1-9 under consideration to the extent that they read on, or are generic to the elected invention. Claims 10-12 are withdrawn as to non-elected inventions. Claims 1-9 were rejected in the prior action, mailed on December 17, 2003. The Applicant submitted a Response on March 16, 2004.

Specification

2. **(Prior Objection- Withdrawn)** The disclosure was objected to because of the following informalities: on page 54, line 16 of the specification, the application indicates that Table 1 discloses the results of the use of an anti-HIV test of the claimed composition. However, Table 1, on page 43, discloses the amino acid profile of a typical blood composition. It appears as though the application should refer to Table 3 in this instance. In view of the amendment of the application, the objection is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(Prior Rejection- Maintained)** Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on immunogenic

compositions comprising a "reduced viral pathogen." It is not clear from the claims or the specification what is meant by the term "reduced." Applicant traverses the rejection on the grounds that the application provides examples of what reduced antigens comprise. However, the Applicant also argues that the reduction of antigens is different from other processing steps such as the denaturation of antigens. However, reducing is considered to include the cooking of antigens, and denaturation is considered to include the heating of antigens, and the specification actually states that the reduction may result in denaturation (page 29, lines 15-16). Thus, the term "reduced" appears to overlap with the term "denatured." However, the Applicant argues that they are different, but provides no means by which to distinguish antigens produced by "reducing" from those resulting from "denaturation."

Additionally, the Applicant argues that the examples provided in the application demonstrate what "reducing" means. In particular, the Applicant refers to lines 9-13 on page 29. However, the provided list does not appear to be exhaustive. See, line 10 (noting that reducing "comprises a process including" any of those listing, but not stating that it is limited to such processes). Additionally, it is not clear that each of the listed processes results in the same or a similar antigen composition. For example, it is not clear that cooking or oxidizing would result in the same forms of compositions as either enzyme digestion or ion exchange chromatography. Because it is not clear what the common element among the various "reduction" processes is, and because it is not clear what the structural characteristics of a reduced antigen are, the rejection is maintained.

5. **(Prior Rejection- Withdrawn)** Claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear what was meant by the phrase "fungi influenza virus." In view of the amendment of the claim to insert a comma between the terms fungi and influenza virus, the rejection is withdrawn.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Restated and Maintained)** Claims 3-9 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising an inactivated influenza virus, does not reasonably provide enablement for vaccine compositions, or compositions inducing immunity against, any viral pathogen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The Applicant traverses the rejection on the basis that claims exclude the use of live viruses. However, the term "reduced" in claim 3 does not require that the virus inactivated. Rather, the term "reduced" has been described in the application as merely requiring the "drying" of the pathogen. Thus, the claim does not appear to require its inactivation. Further, claim 5 reads on an immunogen. The term "immunogen" is understood in the art to include any substance capable of inducing an immune response. There is nothing the application to indicate a narrower definition in the present claims. Further, it is known in the art that whole viruses can induce an immune

response. Thus, there is nothing to exclude whole live virus in the claimed compositions. The Applicant's arguments in traverse are therefore not found persuasive.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **(Prior Rejection- Maintained)** Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by Avtushenko et al., J Biotechnol 44: 21-28. Applicant traverses the rejection on the grounds that claims 1 and 2 require heat inactivation of the viral pathogen, and that the reference does not teach heat inactivation. This argument in traversal is not found persuasive because the claims are drawn to a composition, and not to a method of making the composition. It is not clear how the claimed compositions are structurally distinct from those of the Avtushenko reference. As the Applicant has provided no evidence that the claimed invention varies from that taught by Avtushenko, the rejection is maintained.

10. **(Prior Rejection- Maintained)** Claims 3-5, and 7-8 were rejected under 35 U.S.C. 102(a) as being anticipated by Barrett et al. (WO 00/47222, see, U.S. Patent 6,635,246 for

English translation of the specification of the reference). These claims read broadly on immunogenic compositions comprising a reduced influenza virus (see above), or an immunogen derived from an influenza virus. The Applicant traverses the rejection on two grounds. First, the Applicant argues that the composition of the reference is made through denaturation. This argument is not found persuasive for the reasons indication with respect to the Avtushenko reference above. I.e., the Applicant has not demonstrated that the compositions of the prior art are structurally distinct from those of the present application. See also, the indefiniteness rejection above.

The Applicant also argues that the Barrett reference teaches the inclusion of an adjuvant. The Applicant argues that such inclusion was necessary to induce immunity, and that the claimed invention does not require an adjuvant to induce an immune response. This argument is not found persuasive as none of the rejected claims excludes the use of an adjuvant. Claim 6, which requires that there be no adjuvant was not rejected over this reference. The Applicant is therefore arguing that the reference fails to show certain features of applicant's invention which are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, under the doctrine of claim differentiation, the Applicant's inclusion of claim 6 in the claim set indicates that the other claims are intended to read on embodiments wherein the composition includes an adjuvant. The argument is therefore not found persuasive.

For these reasons, and the reasons of record, the rejection is maintained.

11. **(Prior Rejection- Maintained)** Claims 5-8 were rejected under 35 U.S.C. 102(b) as being anticipated by Waldman et al. (Am J Med Sci 292: 367-71). These claims read on oral immunogenic compositions comprising an influenza antigen. Waldman teaches such a composition on page 368. The Applicant traverses the rejection on the basis that the reference fails to teach the induction of an immune response in naïve (to influenza vaccination) population. However, as was indicated above, the claims are drawn to a composition, and not to a method. The Applicant has not provided any structural differentiation between the composition of Waldman, and those of the rejected claims. Because the composition of Waldman appears to meet the limitations of the rejected claims, the burden is on the Applicant to establish that the composition of the prior art differs from that of the claims. Because there is no evidence to support a finding of any such difference, the rejection is maintained.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **(Prior Rejection- Maintained)** Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Zakay-Rones et al. (WO 97/14434) or Dutcher et al. (U.S. Patent 3,060,094), either of these references in view of Smith et al. (U.S. Patent 6,245,532), or

Avtushenko, and further in view of Sokoll et al. (U.S. Patent 6,623,764). Claims 1-9 read on immunogenic compositions formulated for oral administration or as oral pills.

It is first noted that the rejection is bases on the teachings of Zakay-Rones or Dutcher, in view of either of Smith or Avtushenko, and further in view of Sokoll. This indicates that the teachings of Zakay-Rones are redundant, with respect to the present claims, to the teachings of Dutcher. The same applies to Smith and Avtushenko. Thus, only three references are required to achieve the claimed inventions. The Applicant argues that the Examiner has applied improper hindsight to combination of these references. The Applicant argues that there is no motivation to combine Sokoll with the teachings of the other references. The Applicant bases this assertion on the fact that the Sokoll reference has been classified differently from the other references. This argument is not found persuasive. The reference explicitly teaches that the particles disclosed therein may be used for the delivery of immunogenic compositions. The other references disclose or suggest such compositions. It would therefore have been obvious to those in the art to use the particles of Sokoll to deliver the compositions of the other references. As the Applicant has provides no grounds other than the separate classifications as to why those in the art would not have been motivated to combine the references despite the suggestion in Sokoll that it may be combined with such teachings regarding immunogenic compositions, the argument is not found persuasive.

In addition to the assertion of no motivation to combine, the Applicant also provides two further arguments in traversal. The first of these is that 'reliance of an large number of references "without more" ' is an improper basis for a rejection. Response, page 13 (quoting *In re* Gorman, 18 U.S.P.Q. 2d 1885). The "without more" referred to by Gorman appears to be any teaching in

the art, or in the references, suggesting the combination of the references. *Gorman*, 18 U.S.P.Q. 2d at 1889. In particular, the Gorman case found that the various limitations of the claims under consideration were taught "in substantially the same manner, in devices in the same field of endeavor" in the references cited in that case. Such is also the case in the present application. The claimed antigens are taught or suggested by Zakay-Rones or Dutcher, in view of either of Smith or Avtushenko. The pill or capsule form for the administration of the antigens is suggested by Sokoll. Each of these references therefore provides teachings "in the same field of endeavor" (i.e. the induction of an immune response). In view of this, there is sufficient motivation in the references, as indicated in the prior action, for the combination of the references. The Applicant's second argument is therefore not found persuasive.

The Applicant's last argument is a two-part argument concerned with the teachings of Sokoll. In particular, the Applicant argues that this reference does not teach the use of antigens in the absence of the polyester copolymers, and that the reference does not teach the particular antigens claimed. These arguments are not found persuasive. The first argument is not persuasive because there is nothing in the claims that excludes the use of the copolymers in the claimed immunogenic compositions. The second is not persuasive because the traversal is an argument against an individual reference. It has been held that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Because the other references provide the missing teachings, this argument is not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

14. **(Prior Rejection- Maintained)** Claims 5-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sokoll (supra). These claim read on immunogenic compositions comprising an immunogen formulated into a pill. Sokoll has been described above. The Applicant argues that the reference teaches that the Sokoll reference teaches that the copolymer composition "has to be co-administered with another preparation... to neutralize stomach acidity," and that the reference therefore fails to teach the use of an oral pill vaccine that would be immunogenic. However, the reference does not appear to teach that such an additional ingredient is required. Rather, the reference merely teaches that it may be "advantageous" to co-administer the ingredient with it. Further, the Examples of the reference indicate that the compositions are effective for inducing immune responses when administered orally. See e.g., Example 21. The Applicant's argument in traversal is therefore not found persuasive. The rejection is maintained for the reasons above, and the reasons of record.

15. **(Prior Rejection- Maintained in part)** Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of either Barrett as applied above against claims 3-5, 7, and 8, Avtushenko as applied against claim 3-4, or Waldman as applied against claim 5-8. Claim 9 further limits the composition of claim 5 by indicating the immunogen percentage by weight of the claimed pill. As noted by the Applicant, claim 5 was not rejected over Avtushenko, although claim 9 is dependant on claim 5. In view of this, the rejection is withdrawn from this claim. However, claim 5 was rejected over each of Barrett and Waldman. The Applicant's arguments with respect to these references were not found persuasive for the reasons above. As the

Applicant has provided no additional arguments in traversal of the rejection of claim 9, the rejection is maintained over these references.

Conclusion

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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